

June 23, 1998

Office of Special Nutritionals (HFS-450) 3 3 5 3 '98 JUL 20 P1:42 Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington DC 20204

JUN 2 9 1998

Re: Notification of DSHEA nutritional support claim for AmeriFIT Estroven Dietary Supplement

Dear Sir or Madam:

The purpose of this letter is to provide notification pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act ("the Act") and 7 C.F.R. § 101.93 that AmeriFIT, Inc., is marketing a dietary supplement that bears a statement of nutritional support as defined in section 403 (r)(6) of the Act.

The labeling for Saw Palmetto Extract bears the following statements:

"Prostate Support Formula."

"Saw Palmetoo has been used for generations to help support healthy prostate function."

AmeriFIT, Inc. has on file substantiation that the above statements are truthful and not misleading. To the best of my knowledge, the information contained in this notice is complete and accurate.

Sincerely.

Craig Larsen

Director of Product Development and Quality Assurance

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